



# Data Interoperability to Advance Team-Based Care

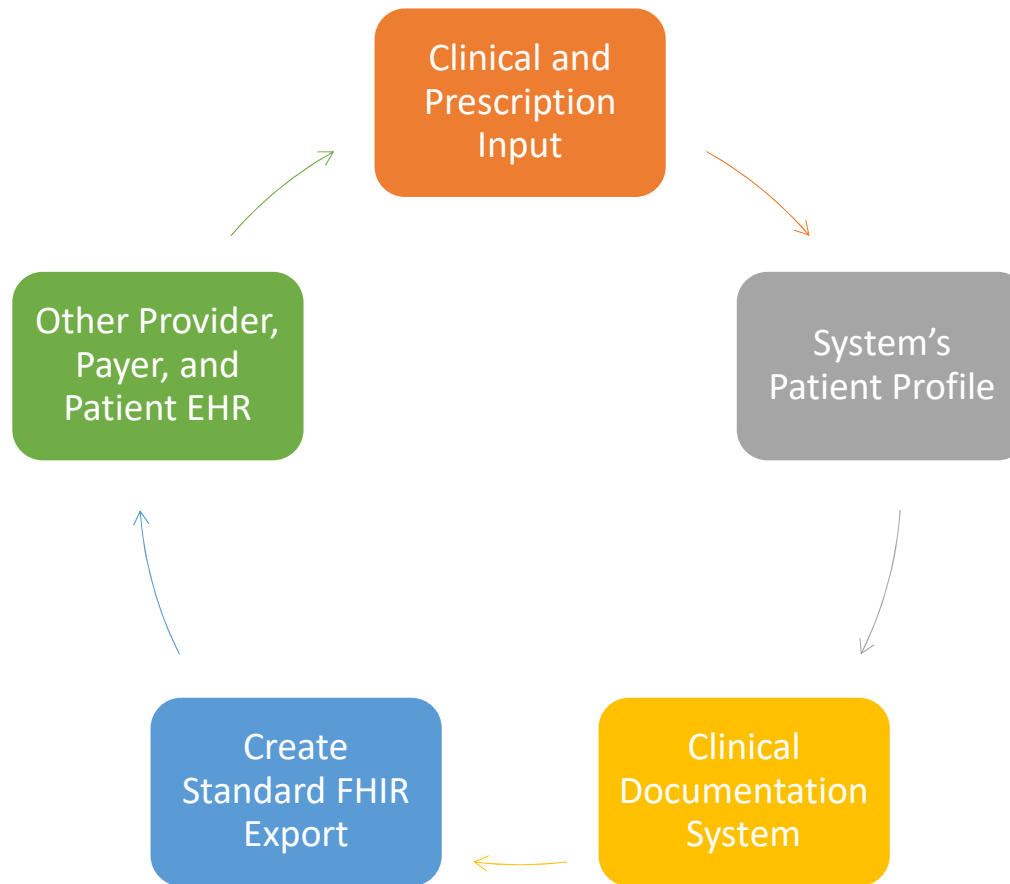
*Current state of data sharing to  
support communications and  
team-based care*

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# Data Sharing to Support Team-Based Care



# The Road to Clinical Data Interoperability

- Regulations
- Standard Vocabulary
- Standard Documents (NCPDP/HL7)
- Workflow and Clinical Decision Support (CDS)

# Data Sharing Regulations

- 2014 Impact Act – Post Acute Care Transitions of Care (ToC)
  - Data Element Library (DEL)
  - PACIO Project
- 21<sup>st</sup> Century Cures – HTI-1
  - Information Blocking
  - Interoperability
    - FHIR and US Core
    - U.S. Core for Data Interoperability (USCDI) v3
    - Interoperability Standards Advisory (ISA)
  - Trusted Exchange Framework and Common Agreements (TEFCA)
    - Qualified Health Information Networks (QHINs)

## Medications

Pharmacologic agents used in the diagnosis, cure, mitigation, treatment, or prevention of disease.

## Medications

Dose

Dose Units of Measure

Indication

Fill Status



# Regulations – HTI-1

## Health Data, Technology, and Interoperability (HTI-1)

Certification Program  
Updates, Algorithm  
Transparency, and  
Information Sharing

Proposed Rule  
comments due June 12

- *Implementing the Electronic Health Record Reporting Program as new Condition and Maintenance of Certification requirements (Insights Condition) for developers of certified health information technology (health IT) under the Certification Program.*
- *Modifying and expanding exceptions in the information blocking regulations to support information sharing and certainty for regulated actors.*
- *Revising several Certification Program certification criteria, including existing criteria for clinical decision support (CDS), patient demographics and observations, electronic case reporting, and application programming interfaces for patient and population services.*
- *Raising the baseline version of the United States Core Data for Interoperability (USCDI) from Version 1 to Version 3.*
- *Updating standards adopted under the Certification Program to advance interoperability, support enhanced health IT functionality, and reduce burden and costs.*

# Standard Vocabulary

- Clinical Terms
  - SNOMED CT, LOINC, RxNorm, ICD-10
- NLM Value Set Authority Center (VSAC)
  - PharmacyHIT created 120 value sets

The screenshot shows the NIH National Library of Medicine Value Set Authority Center (VSAC) search interface. The header includes the NIH logo and the text "National Library of Medicine Value Set Authority Center". Below the header is a navigation bar with three tabs: "Welcome", "Search Value Sets" (which is highlighted in orange), and "Download". The main content area features a search prompt: "Search the NLM Value Set Repository." followed by a "Program:" dropdown menu set to "All". Below this is a section for "COVID-19 Value Sets:" with a help icon and a checkbox. A "Refine by:" section contains two dropdown menus: "PharmacyHIT" and "Code System".

# Standard Documents (NCPDP/HI7)

- Implementation Guides (IGs)
- Pharmacist eCare Plan
- Pharmacist Consultation Note
- Future Standardized Medication Profile (SMP) for ToC



# Workflow and Clinical Decision Support

- FDA (Digital Health Center of Excellence) AI/ML based software as a medical device action plan
  - Outlining FDA's oversight of AI/ML-based medical software
  - Population bias, safe and effective
- ONC HTI-1 proposed rule
  - Revise EHR certification criteria for clinical decision support (CDS)
  - Decision Support Interventions (DSI) and Predictive Models (Algorithmic Transparency)
    - Population bias
    - FAVES





## Transparency & Trustworthiness in DSI Proposals

### Transparency

Information about the.....

- (1) use of data related to health equity in predictive DSIs,
- (2) technical and performance aspects of predictive DSIs, and
- (3) organizational competencies employed to manage risks for predictive DSIs.

Transparency would provide essential information needed to determine whether and how to use the predictive model's outputs.

### Trustworthiness

- ONC frames "trustworthy" or "high quality" predictive DSIs as Fair, Appropriate, Valid, Effective, and Safe (FAVES)

<b>Fair</b>	Model does not exhibit prejudice or favoritism toward an individual or group based on their inherent or acquired characteristics.
<b>Appropriate</b>	Model is well matched to specific contexts and populations to which it is applied.
<b>Valid</b>	Model has been shown to estimate targeted values accurately and as expected in both internal and external data.
<b>Effective</b>	Model has demonstrated benefit in real-world conditions.
<b>Safe</b>	Model is free from any unacceptable risks and for which the probable benefits outweigh any probable risk.



# Recommendations



Establish document standards



Expand standardized vocabulary



Create electronic quality measures



Be prepared for regulatory changes



Focus on workflow around clinical decision support to reduce clinician burden

# References

- CMS IMPACT Act of 2014 Data Standardization & Cross Setting Measures <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-Measures>
- ONC Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule <https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program>
- United States Core Data for Interoperability (USCDI) v3 <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi#uscdi-v3>
- National Library of Medicine's (NLM's) Value Set Authority Center (VSAC) <https://vsac.nlm.nih.gov>
- HL7 FHIR <https://www.hl7.org/fhir/>
- HL7 Pharmacist Services and Summaries – FHIR <http://hl7.org/fhir/us/phcp/>
- Pharmacist Consultation Note <https://confluence.hl7.org/display/FHIR/Pharmacist+Consultation+Note+IG>

# References (continued)

- NCPDP/HL7 Standardized Medication Profile  
<https://www.ncdp.org/NCPDP/media/pdf/WhitePaper/Standardization-Medication-Profile-White-Paper.pdf?ext=.pdf>
- FDA Artificial Intelligence and Machine Learning in Software as a Medical Device  
<https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>
- FDA Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML) – Based Software as a Medical Device <https://www.fda.gov/media/122535/download>
- HTI-1 Proposed Rule Information Sessions DSI Proposal  
<https://www.healthit.gov/news/events/hti-1-proposed-rule-information-sessions>



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